Summary Report

Chloral Hydrate

Prepared for:

Food and Drug Administration
Clinical use of bulk drug substances nominated for inclusion on the 503B Bulks List
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Table of Contents

Table of Tables

REVIEW OF NOMINATION

Chloral hydrate (UNII code: 418M5916WG) was nominated for inclusion on the 503B Bulks List by Triangle Compounding Pharmacy, Inc. for use in chronic insomnia via a 100mg/mL oral suspension and up to 500mg capsules. The reasons provided for nomination to the 503B Bulks List is due to the other FDA-approved products are less effective or have an increased risk of side effects.

METHODOLOGY

Background information

The national medicine registers of 13 countries and regions were searched to establish the availability of chloral hydrate products in the United States (US) and around the world. The World Health Organization, the European Medicines Agency (EMA), and globalEDGE were used to identify regulatory agencies in non-US countries. The medicine registers of non-US regulatory agencies were selected for inclusion if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information, specifically, product trade name, active ingredient, strength, form, route of administration (ROA), and approval status provided in a useable format. Based on these criteria, the medicine registers of 13 countries/regions were searched: US, Canada, European Union (EU), United Kingdom (UK), Ireland, Belgium, Latvia, Australia, New Zealand, Saudi Arabia, Abu Dhabi, Hong Kong, and Namibia. Both the EMA and the national registers of select EU countries (Ireland, UK, Belgium, and Latvia) were searched because some medicines were authorized for use in the EU and not available in a member country and vice versa.

Each medicine register was searched for chloral hydrate; name variations of chloral hydrate were entered if the initial search retrieved no results. The following information from the search results of each register was recorded in a spreadsheet: product trade name; active ingredient(s); strength; form; ROA; status and/or schedule; approval date. Information was recorded only for products with strengths, forms and/or ROA similar to those requested in the nominations.

In addition to the aforementioned medicine registers, the DrugBank database (version 5.1.4) and the Natural Medicines database were searched for availability of over-the-counter (OTC) products containing chloral hydrate. The availability of OTC products (yes/no) in the US and the ROA of these products were recorded in a spreadsheet. Individual product information was not recorded.

Systematic literature review

Search strategy

Two databases (PubMed and Embase) were searched including any date through February 12, 2019. The search included a combination of ("chloral hydrate"[TIAB] OR noctec[TIAB] OR "2,2,2-trichloroethane-1,1-diol"[TIAB]) AND (therapy[TIAB] OR therapeutic*[TIAB] OR clinical[TIAB] OR treatment[TIAB] OR insomnia[TIAB] OR anxiety[TIAB] OR hypno*[TIAB] OR sedat*[TIAB] OR sleep*[TIAB] OR anesthe*[TIAB]) AND humans[MeSH Terms] AND English[lang] NOT autism. Peer-reviewed articles as well as grey literature were included in the search. Search results from each database were exported to Covidence®, merged, and sorted for removal of duplicate citations.

Study selection

Literature reviews and/or meta-analyses, cost-effectiveness, and epidemiological studies were excluded. Articles were considered relevant based on the identification of a clinical use of chloral hydrate or the implementation of chloral hydrate in clinical practice. Articles were excluded if not in English, a clinical use was not identified, incorrect salt form, or if the study was not conducted in humans. Screening of all titles, abstracts, and full-text were conducted independently by two reviewers. All screening disagreements were reconciled by a third reviewer.

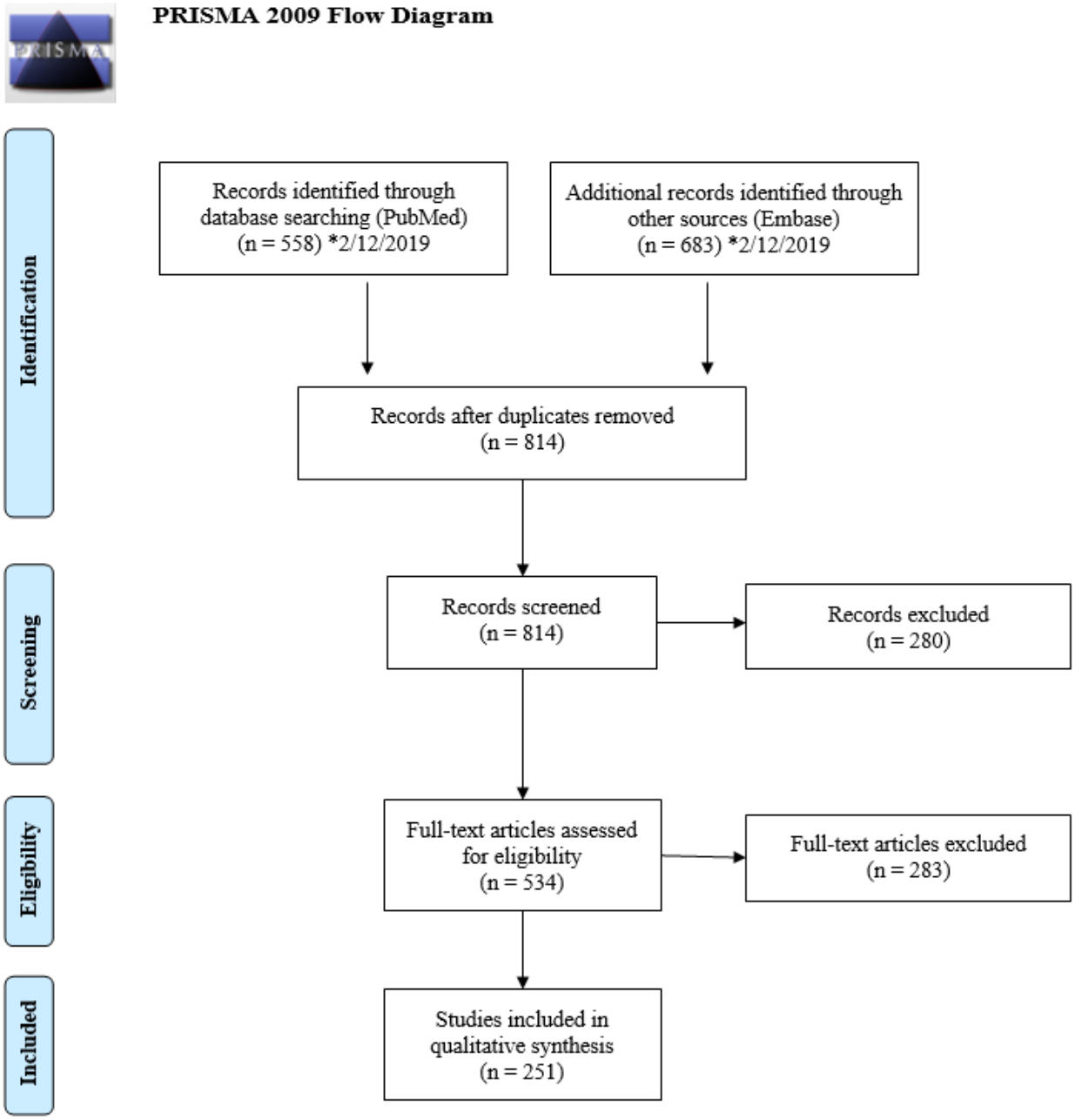
Data extraction

A standard data extraction form was used to collect study authors; article title; year published; journal title; country; indication for chloral hydrate use; dose; strength; dosage form; ROA; frequency and duration of therapy; any combination therapy utilized; if applicable, formulation of compounded products; study design; and any discussion surrounding the use of chloral hydrate compared to alternative therapies.

Results

Please refer to Figure 1.

Figure 1. Summary of literature screening and selection (PRISMA 2009 Flow Diagram)



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Outreach to medical specialists and specialty organizations

Using the indication from the nomination and the results of the literature review, five (5) medical specialties that would potentially use chloral hydrate were identified: anesthesiology, neurology, pediatrics, psychiatry, and sleep medicine. Semi-structured interviews were conducted with subject matter experts within these specialties. Interviews lasted from 30-75 minutes and were conducted either via telephone or in-person. Criteria for selecting subject matter experts included recommendations provided by specialty professional associations, convenient geographic location, authorship within the specialty, or referral by an interviewee. Up to nine (9) interviews were conducted per substance. To determine if a formal interview was warranted, two (2) medical experts, one in neurology and one in psychiatry, were provided the list of substances pertinent to their specialty via email. The psychiatrist replied that they do not utilize any of the substances listed and the neurologist failed to respond to the interview request. Three (3) additional experts in anesthesiology and ophthalmology were contacted for interviews, of which three (3) accepted and zero (0) declined interviews. One (1) interview was recorded and transcribed via ©Rev.com, while two (2) interviews were not recorded. The University of Maryland, Baltimore IRB and the Food & Drug Administration RIHSC reviewed the study and found it to be exempt. Subject matter experts provided their oral informed consent to participate in interviews.

Survey

General professional medical associations and specialty associations for anesthesiology, neurology, pediatrics, psychiatry, and sleep medicine identified from the nomination, literature review, and interviews, were contacted to facilitate distribution of an online survey. A Google™ search was conducted to identify relevant professional associations within each specialty. Associations were included if their members are predominantly practitioners, national associations, and organizations focused on practice within the US. Organizations without practicing physicians and state or regional organizations were excluded. The association's website was searched in order to identify the email of the executive director, regulatory director, media director, association president, board members, or other key leaders within the organization to discuss survey participation. If no contact information was available, the "contact us" tab on the association website was used.

An online survey was created using Qualtrics® software (Provo, UT). The survey link was distributed to seven (7) associations. If an association had more than one (1) substance with indications relevant to that specialty, substances were combined into one (1) survey with no more than 14 substances per survey. Table 1 highlights the associations that agreed to distribute the survey link and Table 2 includes the associations that declined to participate. Additionally, single substance surveys were created and posted on the project website which was shared with survey participants.

Participation was anonymous and voluntary. The estimated time for completion was 30 minutes with a target of 50 responses per survey. The Office of Management and Budget (OMB) approved this project.

Table 1. Participating associations

Specialty	Association
Pediatrics	American Academy of Pediatrics (AAP)

Table 2. Associations that declined participation

Specialty	Association	Reasons for Declining
Anesthesiology	American Society of Anesthesiologists (ASA)	Declined, requires a PI who is an ASA member
Medicine	American Medical Association (AMA)	Failed to respond
	American Osteopathic Association (AOA)	Failed to respond
Neurology	American Academy of Neurology (AAN)	Failed to respond
Psychiatry	American Psychiatric Association (APA)	Declined, "we have put this ask to our members and unfortunately, we have not received any information on psychiatrists using compounded products"
Sleep Medicine	American Academy of Sleep Medicine (AASM)	Failed to respond

CURRENT AND HISTORIC USE

Summary of background information

- Chloral hydrate is not available as an FDA-approved product. Chloral hydrate was available as an unapproved drug in the US; however, it has been removed from the market.
- Chloral hydrate is not available as an OTC product in the US.
- There is a current United States Pharmacopoeia (USP) monograph for chloral hydrate.
- Chloral hydrate is available in Abu Dhabi, Australia, Canada, Hong Kong, and the UK.

Table 3. Currently approved products – US

No approved products in the US

Table 4. Currently approved products–select non-US countries and regions[a]

Active Ingredient	Concentration	Dosage Form	ROA	Approved For Use		
				Country	Status	Approval Date[b]
Chloral hydrate	28.6-200mg/mL	Powder, solution, syrup	Oral	Abu Dhabi	–	–
				Australia	Prescription	11/26/1992
				Canada	Prescription	12/31/1990
				Hong Kong	Prescription	3/31/1984
				UK	Prescription	Marketed since 1957; renewed 12/13/1998

Abbreviations: "–", not mentioned; ROA, route of administration.

[a]Medicine registers of national regulatory agencies were searched if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information (product trade name, active ingredient, strength, form, ROA, and approval status) provided in a useable format. Information was recorded only for products with strengths, forms, and/or ROA similar to those requested in the nominations. See Methodology for full explanation.

[b]If multiple approval dates and/or multiple strengths, then earliest date provided.

Summary of literature review

- Total number of studies included: 251 (20 descriptive, 166 experimental, and 65 observational).
- Most of the studies were from the US (122).
- The most common indications for the use of chloral hydrate in both US and non-US countries was sedation followed by insomnia.
- Compounded products including a 100-200 mg/mL syrup, 1% solution, and 0.5g capsule were identified from the US studies. Compounded products, including suspension, solution, syrups, and tablets, were also identified from the non-US studies.

Table 5. Types of studies

Types of Studies	Number of Studies
Descriptive[1-20]	20
Experimental[21-186]	166
Observational[187-251]	65

Table 6. Number of studies by country[a]

Country	Number of Studies
Australia[26,35,48,113,171]	5
Austria[141]	1
Belgium[1]	1
Brazil[2,7,50,60,65,96]	6
Canada[19,23,36,67,73,100,106,156,169,173,177,201,202,215,231,247]	16
China[14,41,4379,107,108,183,185,186,251]	10
Colombia[200]	1
Czech Republic[12]	1
Egypt[91]	1
France[142,246]	2
Germany[6,127,205,230]	4
Greece[189]	1
Iran[27,28,61-63,77,144]	7

Ireland[222]	1
Israel[11,13,57,216]	4
Italy[20,38,191,192,198,199,224]	7
Jamaica[134]	1
Japan[204]	1
Lebanon[203]	1
Mexico[30,167]	2
New Zealand[9]	1
Pakistan[75]	1
Saudi Arabia[83,84,97,158,187]	5
Singapore[42]	1
South Africa[93]	1
South Korea[99,213,217,218,220]	5
Spain[116,151,152]	3
Switzerland[64,225,240]	3
Taiwan[250]	1
Thailand[104]	1
The Netherlands[80]	1
Turkey[25,33,37,46,72,159]	6
UK[16,18,24,55,66,74,98,102,112,122,131,135,154,160,163,165,170,176,182,184,190,219,227,233,242]	25
US[3-5,8,10,15,17,21,22,29,31,32,34,39,40,44,45,47,49,51-54,56,58,59,68-71,76,78,81,82,85-90,92,94,95,101,103,105,109-111,114,115,118-121,123,125,126,128-130,132,133,136-140,143,145-150,153,155,157,161,162,164,166,168,172,174,175,178-181,188,193-197,206-212,214,221,223,226,228,229,232,234-239,241,243-245,249]	121
Multiple Countries • Canada, UK[248] • China, US[124]	2
	Total US[b]: 129 Total non-US Countries[b]: 122

[a]Study 117 did not mention a country.
[b]Study 124 counted in both US and non-US total.

Table 7. Number of studies by combinations

No combination products were nominated

Table 8. Dosage by indication – US

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Sedation[3,5,10,17,21,22,29,31,34,39,40,44,45,47,49,51-54,56,58,59,68-71,78,82,85-90,94,95,101,105,110,111,114,115,119-121,123-126,128-130,133,136,139,143,145-147,148,150,153,155,157,161,164,166,168,172,174,175,178-181,188,193-197,206-212,214,221,223,226,228,229,232,234-238,239,241,243-245,249]	25-125mg/kg	–	–	–	Once
	15-125mg/kg 25mg/month of age	200mg/ml	Elixir, liquid, solution, syrup	Nasogastric, oral	Once-Twice
	25-100mg/kg	–	Suppository	Rectal	Once
	25-100mg/kg	–	–	Intravenous	–
Insomnia[15,32,76,92,103,109,118,132,137,138,149,162]	0.5-1g	–	–	–	–
	0.25mg/kg 0.25-2g/day	0.5g	Capsule, elixir, tablet	Oral	Once-3 months
	1g/day	1%	Solution		Once
Agitation[81]	–	–	–	Oral	–
Epilepsy[140]	0.5-3g/day	–	Capsule, liquid	Oral	5 months-14 years
Physician assisted suicide[4]	–	–	–	–	–
Reduction of self-injurious behavior[8]	3-4.5g/day	–	–	–	–

Abbreviations: "–", not mentioned; ROA, route of administration.

Table 9. Dosage by indication – non-US countries

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Sedation[1,2,7,9,11,16,19,24-28,30,33,35,37,38,41-43,46,48,50,55,57,60-65,72,73,75,77,79,80,83,84,91,93,96-100,102,104,107,108,113,116,117,122,124,127,131,134,135,141,144,151,152,154,156,158,159,163,165,167,169-171,173,176,182-187,189,190-192,198-201,203,213,215-220,222,224,225,227,230,231,233,240,242,246-248,250,251]	25-120mg/kg 0.5-3.5g 0.3-0.5mL/kg	–	–	–	Once
	20-400mg/kg 0.32-2g 0.5-1mL/kg	5-10% 100-200mg/mL	Elixir, liquid, solution, syrup	Nasogastric, oral	Once-Twice
	11-75mg/kg	1mL/kg	Suspension	Oral	–
	30-125mg/kg	–	–	Rectal	Once
	1mL/kg	10%	Enema		
	75 mg/kg	240mg/ml	Solution		
	15-30mg/kg 5-9mg/kg/hr	–	Liquid	Enteral	7 days
Insomnia[23,36,66,67,106,112,142,160,177,202]	1g/day	–	–	–	3 days
	At most 50mg/kg	0.25-0.26g	Tablet	Oral	2-7 days
	0.5g/day	0.5g	Capsule		5-6 days
Anxiety[25,75]	25-75mg/kg	–	–	–	–
	25mg/kg	100mg/mL	Solution	Oral	Once
Neonatal abstinence syndrome[6,205]	40-160mg/kg/day	–	–	–	–
	30-150mg/kg/day	–	–	Nasogastric	14 days

Agitation[19]	70mg/kg 0.25g/4 hours as needed	–	–	–	–
Alternating hemiplegia of childhood[20]	0.6g	–	–	Rectal	–
Benign Convulsions[204]	0.25-0.5g	0.25-0.5g	Suppository	Rectal	Once
Dyskinesia[18]	–	–	–	–	–
Focal epilepsy[14]	–	–	Enema	Rectal	–
Intractable status epilepticus[13]	20-30mg/kg	–	Rectal	–	–
Neonatal seizure[74]	30mg/kg	–	–	–	–
Ohtahara syndrome[12]	58mg/kg/day	–	Syrup	–	25 days

Abbreviations: "–", not mentioned; ROA, route of administration.

Table 10. Compounded products – US

Indication	Publication Year	Compounding Method	Dosage Form	Final Strength
Sedation[3,59,249]	1961, 1964, 2014	• "Prepared in a thick, clear liquid containing approximately 100 mg/mL"[3]	Syrup	100mg/mL
		• In flavored syrup[59]		–
		• Mixture of 500 cc of strawberry flavored syrup, 250 cc sterile water, and 150 grams of chloral hydrate prepared by the pharmacy[249]		200mg/mL
Insomnia[132]	1955	• Administered in gelatin capsules containing 0.5 g of chloral hydrate with polyethylene glycol 400 as the vehicle	Capsule	0.5g
		• Prepared as 1% (w/v) aqueous solution, a small amount (1 part in 250) of aromatic fluid extract of eriodictyon to mask the drug from placebo	Solution	1%

Table 11. Compounded products – non-US countries

Indication	Compounding Method	Dosage Form	Final Strength
Sedation[25,50,97,134,224,230]	• "Prepared by a pharmacist and given in a suspension of 1 mL/kg"[50]	Suspension	1mL/kg
	• Pharmacy prepared solution containing 150 g of chloral hydrate, 250 cc of sterile water, and 500 cc of strawberry flavored syrup[97]	Solution	–
	• In 20 mL of freshly prepared, cherry-flavored liquids[25]		80-160mg/mL
	• Chloral hydrate dissolved in 70% sucrose[230]		
	• "Galenic preparation"[224]	–	
	• 30 grains of chloral hydrate in 1 ounce rum and 1 ounce syrup[134]	Syrup	–
Insomnia[112]	• Chloral hydrate 250 mg compounded with paracetamol 275 mg and hydratene	Tablet	0.25g
Anxiety[25]	• In 20 mL of freshly prepared, cherry-flavored liquids	Solution	100mg/mL

Summary of focus groups/interviews of medical experts and specialty organizations

Two (2) interviews were conducted. One (1) interview was conducted with two (2) interviewees and was not recorded. In addition, a medical expert in psychiatry was provided a list of substances, including chloral hydrate, pertinent to their specialty via email. The psychiatrist replied that they did not use chloral hydrate. A medical specialist in neurology failed to respond to the interview request.

Table 12. Overview of interviewees

Interviewee	Level of Training	Specialty	Current Practice Setting	Experience with Chloral Hydrate	Interview Summary Response
ANE_01	MD	Anesthesiology	Trauma center	Yes	• There is a need for chloral hydrate because it allows for REMs sleep • Would give to anyone who needs a hypnotic • Would use the previous concentration available (it was taken off the market)
ANE_02	NP	N/A	Trauma center	Yes	• There is a need for chloral hydrate because it allows for REM sleep • Would give to anyone who needs a hypnotic • Would use the previous concentration available (it was taken off the market)
OPH_05	MD	Ophthalmology (retina specialist)	Academic medical institution	No	• Does not use this substance.

Abbreviations: MD, Doctor of Medicine; NP, Nurse Practitioner.

Summary of survey results

Table 13. Characteristics of survey respondents [18 people responded to the survey[a]]

Board Certification	MD	PharmD	No Response
Anesthesiology	7	0	0
Clinical Pharmacology	1	0	0
Critical Care Medicine	3	0	0
Gastroenterology	1	0	0
Hospice & Palliative Medicine	1	0	0
Pediatrics	5	0	0
Pediatrics Anesthesiology	3	0	0
No Board Certification	1	1	0
No Response	0	0	6

Abbreviations: MD, Doctor of Medicine; PharmD, Pharmacist.
[a]Some respondents reported more than one terminal clinical degree or board certification.

Table 14. Types of products used, prescribed, or recommended

Types of Products	Respondents, n (N=4[a])
Compounded	2
FDA-approved	1
Over-the-counter	0
Dietary	0
Unsure	0
No response	1

[a]Out of 18 respondents, four (4) reported using, prescribing, or recommending choral hydrate products.

Table 15. Compounded use of chloral hydrate in practice[a]

Indication	Strength	Dosing frequency[b]	Dosage Form	ROA	Duration of Treatment	Patient Population
Pediatric pulmonary function testing	5mg/ml	"Repeat once in 30 minutes"	Solution	Oral	60-120 minutes	Children

Abbreviation: ROA, route of administration.
[a]One (1) respondent.
[b]Quotations are direct words from respondents.

Table 16. Indications for which chloral hydrate is considered standard therapy

Indication	Standard Therapy		
	Compounded, n (N=2)	Non-compounded, n (N=1)	No Response, n (N=1)
Sedation for pulmonary function testing in children	0	1	0
No response	2	0	1

Table 17. Reasons for using a compounded product instead of any FDA-approved product

Reasons
"One of the options"

Table 18. Change in frequency of compounded chloral hydrate usage over the past 5 years

	Respondents, n (N=2)
No–use has remained consistent	1
Yes–I use it LESS often now	0
Yes–I use it MORE often now	0
No Response	1

Table 19. Do you stock non-patient specific compounded chloral hydrate in your practice?

No survey respondents provided this information

Table 20. Questions related to stocking non-patient specific compounded chloral hydrate

No survey respondents provided this information

CONCLUSION

Chloral hydrate (UNII code: 418M5916WG) was nominated for inclusion on the 503B Bulks List by Triangle Compounding Pharmacy, Inc. for use in chronic insomnia via a 100mg/mL oral suspension and up to 500mg capsules. Chloral hydrate has been removed from the market in the US, but is available in Abu Dhabi, Australia, Canada, Hong Kong, and the UK.

From the literature review, the most common indications in both US and non-US countries were sedation, followed by insomnia. Compounded products (100-200 mg/mL syrup, 1% solution, and 0.5g capsules) were identified from US studies. Compounded products, including suspension, solution, syrups, and tablets, were also identified from the non-US studies.

From the interviews, one interviewee did not use the substance while the other interviewee saw a need for chloral hydrate because it allows for patients to get into REM sleep. The interviewees expressed that they would give it to anyone who needs a hypnotic at the previous approved concentration. The psychiatrist emailed stating that they do not use chloral hydrate.

From the survey responses, four (4) out of 18 respondents used chloral hydrate. Two (2) respondents used compounded chloral hydrate; one (1) of these respondents used chloral hydrate for pediatric patients undergoing pulmonary function testing.

APPENDICES

Appendix 1. References

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Appendix 2. Survey instrument

Start of Block: Welcome Page

The University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI), in collaboration with the Food and Drug Administration (FDA), is conducting research regarding the use of certain bulk drug substances nominated for use in compounding by outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act. In particular, we are interested in the current and historic use of these substances in clinical practice. This survey is for **chloral hydrate**. As a medical expert, we appreciate your input regarding the use of this substance in your clinical practice. This information will assist FDA in its development of a list of bulk drug substances that outsourcing facilities can use in compounding under section 503B of the Act. All responses are anonymous.

OMB Control No. 0910-0871
Expiration date: June 30, 2022

The time required to complete this information collection is estimated to average 30 minutes, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. If you have additional questions or concerns about this research study, please email: compounding@rx.umaryland.edu. If you have questions about your rights as a research subject, please contact HRPO at 410-760-5037 or hrpo@umaryland.edu.

End of Block: Welcome Page

Start of Block: Chloral hydrate

Q1. What type(s) of product(s) do you use, prescribe, or recommend for **chloral hydrate**? Please check all that apply.

- ☐ Compounded drug product
- ☐ FDA-approved drug product
- ☐ Over the counter drug product
- ☐ Dietary supplement (e.g. vitamin or herbal supplement products sold in retail setting)
- ☐ Unsure

Skip To: Q13 If What type(s) of product(s) do you use, prescribe, or recommend for chloral hydrate? Please check all th... != Compounded drug product

Skip To: Q2 If What type(s) of product(s) do you use, prescribe, or recommend for chloral hydrate? Please check all th... = Compounded drug product

---

Display This Question:

If What type(s) of product(s) do you use, prescribe, or recommend for chloral hydrate? Please check all th... = Compounded drug product

Q2. Please list any conditions or diseases for which you use compounded **chloral hydrate** in your practice. Please include the strength(s), dosing frequency(ies), dosage form(s), route(s) of administration, duration of therapy, and patient population (ex. age, gender, comorbidities, allergies, etc).

	Strength(s) (please include units)	Dosing frequency(ies)	Dosage form(s)	Route(s) of administration	Duration of therapy	Patient population
Condition 1 (please describe)						
Condition 2 (please describe)						
Condition 3 (please describe)						
Condition 4 (please describe)						
Condition 5 (please describe)						

Q3. Do you use compounded **chloral hydrate** as a single agent active ingredient, or as one active ingredient in a combination product? Please check all that apply.

- ☐ Single
- ☐ Combination

Skip To: Q5 If Do you use compounded chloral hydrate as a single agent active ingredient, or as one active ingredient... != Combination

Display This Question:

If Loop current: Do you use compounded chloral hydrate as a single agent active ingredient, or as one active ingredient... = Combination

Q4. Please list all combination products in which you use compounded **chloral hydrate**.

_____

Q5. For which, if any, diseases or conditions do you consider compounded **chloral hydrate** standard therapy?

_____

Q6. Does your specialty describe the use of compounded **chloral hydrate** in medical practice guidelines or other resources?

_____

Q7. Over the past 5 years, has the frequency in which you have used compounded **chloral hydrate** changed?

- ○ Yes - I use it **MORE** often now (briefly describe why) _____
- ○ Yes - I use it **LESS** often now (briefly describe why) _____

- No - use has remained consistent

Q8. Why do you use compounded **chloral hydrate** instead of any FDA-approved drug product?

_____

Q9. Do you stock non-patient-specific compounded **chloral hydrate** in your practice location?

- Yes
- No

Skip To: End of Block If Do you stock non-patient-specific compounded chloral hydrate in your practice location? = No

Display This Question:

If Do you stock non-patient-specific compounded chloral hydrate in your practice location? = Yes

Q10. In what practice location(s) do you stock non-patient-specific compounded **chloral hydrate**? Please check all that apply.

- ☐ Physician office
- ☐ Outpatient clinic
- ☐ Emergency room
- ☐ Operating room
- ☐ Inpatient ward
- ☐ Other (please describe) _____

Q11. How do you obtain your stock of non-patient-specific compounded **chloral hydrate**? Please check all that apply.

- ☐ Purchase from a compounding pharmacy
- ☐ Purchase from an outsourcing facility
- ☐ Compound the product yourself
- ☐ Other (please describe) _____

Q12. Why do you keep a stock of non-patient-specific compounded **chloral hydrate**? Please check all that apply.

- ☐ Convenience
- ☐ Emergencies
- ☐ Other (please describe) _____

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded chloral hydrate? Please check all that apply. = Convenience

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded chloral hydrate? Please check all that apply. = Emergencies

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded chloral hydrate? Please check all that apply. = Other (please describe)

Q13. For which, if any, diseases or conditions do you consider **chloral hydrate** standard therapy?

_____

Q14. Does your specialty describe the use of **chloral hydrate** in medical practice guidelines or other resources?

_____

End of Block: Chloral hydrate

Start of Block: Background Information

Q15. What is your terminal clinical degree? Please check all that apply.

- ☐ Doctor of Medicine (MD)
- ☐ Doctor of Osteopathic Medicine (DO)
- ☐ Doctor of Medicine in Dentistry (DMD/DDS)
- ☐ Naturopathic Doctor (ND)
- ☐ Nurse Practitioner (NP)
- ☐ Physician Assistant (PA)
- ☐ Other (please describe) _____

Q16. Which of the following Board certification(s) do you hold? Please check all that apply.

- ☐ No Board certification
- ☐ Allergy and Immunology
- ☐ Anesthesiology
- ☐ Cardiovascular Disease
- ☐ Critical Care Medicine
- ☐ Dermatology
- ☐ Emergency Medicine
- ☐ Endocrinology, Diabetes and Metabolism
- ☐ Family Medicine
- ☐ Gastroenterology
- ☐ Hematology
- ☐ Infectious Disease
- ☐ Internal Medicine
- ☐ Medical Toxicology
- ☐ Naturopathic Doctor
- ☐ Naturopathic Physician
- ☐ Nephrology
- ☐ Neurology
- ☐ Obstetrics and Gynecology
- ☐ Oncology
- ☐ Ophthalmology
- ☐ Otolaryngology
- ☐ Pain Medicine
- ☐ Pediatrics
- ☐ Psychiatry
- ☐ Rheumatology
- ☐ Sleep Medicine
- ☐ Surgery (please describe) _____
- ☐ Urology
- ☐ Other (please describe) _____

End of Block: Background Information